May 2, 2025

VIA ECF

The Honorable Virginia K. DeMarchi
United States District Court for the
Northern District of California
San Jose Courthouse, Courtroom 2 – 5th Floor
280 South First Street
San Jose, California 95113

PURSUANT TO SECTION 4(C) OF THE COURT'S STANDING ORDER RE CIVIL CASES

Re: Joint Discovery Dispute Letter Brief Regarding Discovery Into Teva's Conduct in *Teva Pharmaceuticals USA, Inc. v. Corcept Therapeutics, Inc., and Optime Care Inc.*, Case No. 5:24-cv-03567-NW

To the Honorable Judge DeMarchi:

Pursuant to Section 4 of Your Honor's Standing Order for Civil Cases, Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") and Defendant Corcept Therapeutics, Incorporated ("Corcept") submit this joint discovery letter regarding their dispute over whether Teva should be compelled to search for and produce documents related to its own use of practices with respect to the development, marketing, and distribution of drugs other than generic mifepristone, the drug Teva claims Corcept excluded from the market. *See* Corcept RFPs 1, 6, 15, 16, 22, 43, 44, 45, 46, 47, 59. The parties have engaged in discussions regarding this discovery over the course of two months, including a lead-counsel meet-and-confer on April 21, 2025, but they remain at an impasse. The parties therefore request Your Honor's assistance in resolving this dispute.

1. Statement of Dispute Requiring Resolution

Corcept seeks to compel Teva to search for and produce documents regarding Teva's drug development, marketing, and distribution of branded and generic drugs—including documents relating to Teva's: (i) listing of patents in the FDA's Orange Book, (ii) maintaining patent infringement suits, (iii) payment of speaker fees, and (iv) exclusive dealing agreements. Teva objects to independently searching for such documents regarding its non-mifepristone drugs.

2. Parties' Position Statements

(a) Corcept's Position

Overview. Teva claims Corcept excluded Teva's generic mifepristone from the market by: (1) listing patents in the FDA's Orange Book, (2) asserting patent infringement claims against Teva, (3) entering an "exclusive" agreement with a pharmacy (Optime), and (4) operating a physician speaker program. Courts evaluate this conduct by examining its reasonableness and

consistency with industry norms. Teva must prove Corcept's acts were unreasonable and they—not Teva's own decisions—caused Teva harm. Corcept's defenses thus include (among others) that: (a) its practices are consistent with industry standards, and (b) Teva's generic failed due to Teva's own strategies and lack of physician/patient support. Corcept seeks discovery into Teva's Orange Book listing, patent litigation, exclusive dealing, and physician payment practices (the same type of Corcept conduct Teva challenges). This discovery is relevant to exploring: (i) the falsity of Teva's allegations (Dkt. 39, "FAC") that Corcept's practices are "highly unusual" or "outside the norm," (ii) whether Corcept's actions are reasonable and consistent with industry standards, and (iii) whether Teva's failure to engage in these practices—which it uses for at least some of its branded and generic drugs, but apparently not its mifepristone—is the source of its alleged harm. Teva unquestionably engages in this conduct (indeed, some of these instances are identified in RFP No. 1). In those instances, Teva defends its conduct as lawful and consistent with industry norms (but has an about-face when Corcept does so). Teva's refusal to search for and produce these materials should be rejected.

Relevance. There is a "low threshold for relevance [under] Rule 26." *Wit v. United Behav. Health*, 2016 WL 258604, at *11 (N.D. Cal. Jan. 21, 2016). The Ninth Circuit recognizes an antitrust defendant can present "***evidence of [a] plaintiff's acceptance and advocacy of the restrictions challenged*** as relevant to the question of the reasonableness of the restrictions." *First Beverages, Inc. of Las Vegas v. Royal Crown Cola Co*, 612 F.2d 1164, 1173 (9th Cir. 1980). Courts thus allow discovery into an antitrust plaintiff's use of practices similar to those it claims are anticompetitive. *In re Cathode Ray Tube (CRT) Antitrust Litig.,* 2015 WL 12952688, at *2–3 (N.D. Cal. Jan. 16, 2015) (allowing discovery into plaintiff's similar practices "to rebut allegations that [such practices] are indicative of" anticompetitive conduct); *In re Packaged Seafood Prods. Antitrust Litig*., 2018 WL 4327876, at *3 (S.D. Cal. Sept. 10, 2018) (same, "to counter Plaintiffs' theory" regarding whether conduct "necessarily illegitimate or illegal" or instead "innocuous"); *In re Urethane Antitrust Litig*., 2011 WL 1327988, at *6 (D. Kan. Apr. 5, 2011) (same, defendants " entitled to rebut [plaintiff's] evidence by showing that because plaintiffs engaged in the same conduct, that evidence does not necessarily indicate or support the existence of" anticompetitive conduct); *In re Diisocyanates Antitrust Litig*., 2024 WL 521221, at *3 (W.D. Pa. Feb. 9, 2024) (same, to show conduct "'competition-enhancing' and consistent with industry norms.").

The requested discovery is relevant to Corcept's defenses to each of Teva's theories:

- *Orange Book*: Teva alleges Corcept listed two patents in the Orange Book in bad faith, triggering a 30-month stay of Teva's FDA approval. Orange Book claims are defendable by showing the listing was due to "a ***reasonable, good-faith*** attempt to comply with the Hatch-Waxman scheme." *In re Lantus Direct Purchaser Antitrust Litig*., 950 F.3d 1, 14 (1st Cir. 2020). A relevant factor is "custom and practice in the industry." *Id.* at 13. Therefore, evidence regarding what Teva contends is a proper basis to list a patent in the Orange Book and its own history of construing Orange Book listing requirements liberally—*Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of New York, LLC*, 124 F.4th 898, 910–12 (Fed. Cir. 2024)—is relevant to this inquiry and Corcept's defenses.

- *Sham Litigation*: Teva contends Corcept baselessly sued Teva in prior patent infringement litigation. To succeed on its "sham" theory, Teva must show, *inter alia*, Corcept's claims were "objectively baseless" such that "***no reasonable litigant*** could realistically expect

success on the merits[.]" *Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc*., 508 U.S. 49, 60–61 (1993). Teva's beliefs as to proper bases for a drug manufacturer to sue for patent infringement is pertinent to what a "reasonable litigant" would do and thus Corcept's defense that its bases for bringing similar claims against Teva were objectively reasonable.

- *Exclusive Dealing*: Teva alleges Corcept has an "exclusive" distribution agreement with Optime preventing distribution of Teva's mifepristone. A relevant factor in assessing such an agreement is "the extent to which competitors also employ exclusive dealing arrangements[.]" ABA, *Antitrust Law Developments*, § 1D-2-b. Moreover, Teva alleges Corcept's Optime arrangement is "***highly unusual*** in the pharmaceutical industry." FAC ¶ 147. Teva's use of similar arrangements—which Congress has noted (https://tinyurl.com/2u84c69r at 36–37)—bears on: (a) the Corcept-Optime agreement's reasonableness; and (b) the veracity (or lack thereof) of Teva's claim the agreement is "unusual" in the "pharmaceutical industry."

- *Physician Payments*: Teva claims Corcept's compensating physicians to educate the medical community about Cushing's Syndrome are "bribes" to prescribe Corcept's Korlym over Teva's generic and Corcept's payments are "far outside the norm." FAC ¶ 184. Teva's own use and amount of similar payments to physicians for its own drugs—fees which Teva itself has described as "unremarkable," "customary," and a "benefit" to patients (*United States v. Teva Pharms. USA, Inc*., 13-cv-3702 (S.D.N.Y.), Dkts. 33 at 1–3, 141 at 9–10)—is thus relevant to refuting: (a) the notion Corcept's payments are "outside the norm"; and (b) the inference that the fact or amount of a speaker payment says anything untoward.

Teva's arguments are unavailing. It claims evidence concerning its own practices is irrelevant because it goes to an unavailable "*in pari delicto*" defense. But that misunderstands the purpose of the discovery, which Corcept seeks for the purpose ***allowed*** by Ninth Circuit: to show Teva's "acceptance and advocacy of the restrictions challenged as relevant to … the reasonableness of the restrictions." *Beverages*, 612 F.2d at 1173. Corcept is not—as Teva misstates—asserting an *in pari delicto* defense, because Corcept is "not arguing that Plaintiff[] should be barred, as a matter of law, from recovery because of Plaintiff['s] own conduct," but instead seeks this discovery "to persuade the finder of fact on what inferences to make (or not) based on" ***Corcept's*** conduct. *Seafood*, 2018 WL 4327876, at *3 (rejecting Teva's argument).

Teva also claims Corcept's requests are irrelevant because they relate to non-mifepristone drugs. That misses the point. Teva's allegations are that Corcept's practices are out of the norm in the "***pharmaceutical industry***," which obviously includes a large number of different drugs (including Teva's non-mifepristone drugs). And Teva's use and defense of similar conduct shows that conduct is not unreasonable or illegitimate (regardless of whether Teva's similar conduct occurred with respect to mifepristone or another drug). Moreover, the at-issue practices are often employed for ***branded*** (not generic) drugs. Therefore, Teva's promise to produce such materials with respect to its ***generic*** mifepristone—a drug for which Teva has listed no patents in the Orange Book, asserted no infringement claims, apparently created no speaker program, and perhaps entered no exclusive dealing agreements (though it has them for other drugs)—would likely yield an empty set. Finally, as to Teva's non-mifepristone drugs (branded or generic), Corcept is entitled to discover what—if any—practices Teva used for those drugs compared to mifepristone; contrary to Teva's argument that such non-mifepristone practices "would not shed light on" why Teva's

mifepristone has failed, such discovery is pertinent to Corcept's causation defense—*i.e.*, failure of Teva's mifepristone is due to Teva's not using the same practices that it uses to succeed as to its other non-mifepristone drugs, not Corcept. Teva's proposal to produce documents regarding its mifepristone practices provides no baseline to compare why Teva's other drugs have succeeded but its mifepristone has not.

Burden. Teva has made no actual showing of undue burden. Its objection is poorly-taken considering Teva seeks hundreds of millions of dollars in damages (before trebling), Teva served ***231*** document requests and ***31*** interrogatories on Defendants, and the requested discovery is critical to Corcept's defenses. Teva also baselessly claims "Corcept's requests would require adding countless custodians" and implicate "generic search terms that would hit on countless documents," but Teva: (a) can produce non-custodial materials to address those concerns; and (b) anyway refused to even entertain custodians or search terms related to these topics due to this gating issue, making its predictions mere speculation (which, again, Corcept is happy to address through reasonable and tailored custodians and search terms). Teva made no effort whatsoever to substantiate its burden objections, so they should be overruled.[1]

(b) Teva's Position

Corcept claims it is entitled to vast discovery about Teva's practices in four broad categories for products ***other than Mifepristone***. Corcept's arguments are unconvincing. First, Corcept argues this discovery "is relevant to exploring" whether Corcept's actions are "highly unusual" or "consistent with industry standards[.]" Corcept does not need Teva's documents to prove whether its actions are "highly unusual" or align with "industry standards." And proving industry standards is no basis to open the floodgates of discovery into issues that, for the reasons described below, have minimal (if any) relevance to the issues in this case. Second, Corcept claims this discovery is relevant to "whether Teva's failure to engage in these practices … is the source of its alleged harm." But Teva's policies and practices for 500 ***other*** drugs would not shed light on whether Teva's own conduct limited its ability to gain market share ***with Mifepristone***. Such a demand invites mini trials on hundreds of other irrelevant markets, rather than focus on the anticompetitive conduct and effects in the relevant market.

Relevance. Corcept's relevance arguments appear to be a thinly veiled attempt to mount a whataboutism defense based on Teva's supposedly similar behavior in inapposite situations. But the very case cited by Corcept explains that a "plaintiff's illegal conduct cannot be raised as a complete bar to his antitrust action." *First Beverages*, 612 F.2d at 1174-75 (*in pari dilecto* and unclean hands have been rejected as defenses to Sherman Act claims). "The alleged illegal conduct of [plaintiff cannot] legalize the unlawful combination by [defendants] nor immunize them against liability to those they injured." *Kiefer-Stewart Co. v. Joseph E. Seagram & Sons, Inc.*, 340 U.S. 211, 214 (1951). Corcept does not dispute that evidence for the purpose of showing the plaintiff's improper conduct is inadmissible. *See First Beverages*, 612 F.2d at 1174-75. It simply argues,

[1] Teva's "promise" to not close its eyes to documents related to its non-mifepristone products if it happens to come across them during other searches is insufficient since it provides zero certainty as to what exists or what Teva will mark as responsive and produce; it is also inconsistent with Teva's duty to reasonably and ***specifically search*** for and produce relevant documents.

unconvincingly, that the broad discovery it seeks is aimed at some purpose *other* than showing the plaintiff's improper conduct.

Corcept relies on *First Beverages*, but that case simply ruled that, even if erroneously admitted, reversal was not merited because the defendant in that case did not actually present an *in pari dilecto* or unclean hands argument. *Id.* Moreover, the quotation's reference to the "restrictions challenged" makes clear that they were ***the same restrictions*** that the plaintiff challenged, not some other restrictions that plaintiff allegedly employed for unrelated products in different markets. At best, *First Beverages* recognizes that plaintiff's acceptance of ***the restrictions challenged in that case*** might have some bearing on their reasonableness. But that says nothing about other restrictions for other products, which is what Corcept demands here.

The other unpublished district court cases Corcept cites share that distinction—they, to differing degrees, permit discovery into plaintiff's participation in the same market for the same product, not the plaintiff's other products. *See In re Packaged Seafood Products Antitrust Litigation* 2018 WL 4327876, at *1 (S.D. Cal. Sept. 10, 2018) (discovery of plaintiff's "communications regarding Packaged Tuna," the at-issue product); *In re Cathode Ray Tube (CRT) Antitrust Litigation*, 2015 WL 12952688, at *2 (N.D. Cal. Jan. 16, 2015) (discovery of the plaintiff's sales data and competitive intelligence *for CRT*s); *In re Urethane Antitrust Litigation*, 2011 WL 1327988, at *5 (D. Kan. Apr. 5, 2011) (discovery into plaintiff's downstream price increases based on the product at issue); *In re Diisocyanates Antitrust Litigation* 2024 WL 521221, at *4 (W.D. Pa. Feb. 9, 2024) (discovery into plaintiff's conduct "within the relevant MDI and TDI markets"). Indeed, a court in this district rejected the proposition that an antitrust defendant is entitled to discovery regarding the plaintiff's unrelated marketing practices. *See In re Glumetza Antitrust Litigation,* 2020 WL 3498067, at *12 (N.D. Cal., June 29, 2020).

Orange Book: Corcept claims that Teva's "own history" related to Orange Book listings is relevant to its defenses. Corcept points to *Teva Branded Pharm. Prods. R&D, Inc*., a case where Teva was accused of improper Orange Book listing related to Teva's ProAir HFA Inhalation Aerosol. *See* 124 F.4th 898 (Fed. Cir. 2024). But the *objective* baselessness of Corcept's listing of the '348 and '495 patents is highly fact-dependent and has nothing to do with Teva's *subjective views of other patents*. It instead depends on a claim-by-claim analysis of each patent, and an analysis of the Korlym label, to determine whether the "approved labeling … describes the method(s) of use claimed by the patent." 21 C.F.R. § 314.53(b)(1). Teva's determination of whether unrelated product labels "describe the method(s) of use" claimed by unrelated patents has no bearing on the issues in this case, and certainly has no tendency to make it more or less likely that Corcept's Orange Book listings were improper. Corcept's citation to *Teva Branded Pharm. Prods. R&D, Inc*. makes clear that it intends to mount an improper you-did-it-too defense, which, as explained above, does not justify the discovery.

Sham Litigation: Corcept argues that Teva's subjective views of patent infringement is relevant to whether Corcept's infringement claims were "objectively reasonable." Again, Teva's assertion of unrelated patent claims covering unrelated products is highly fact dependent and has no tendency to make it more or less likely that Corcept's decision to assert *these* patents in *this* case was baseless.

Exclusive Dealing: Corcept claims Teva's use of similar distribution agreements bears on whether the Corcept-Optime Agreement was unreasonable and unusual. Teva acknowledges that Corcept should be able to take discovery into Teva's own distribution agreements *for Mifepristone*. Teva has agreed to produce these documents, and indeed has already produced contracts with distributors, and identified distributors of its generic Mifepristone in its interrogatory responses. Corcept's attempt to seek discovery into all of Teva's own distribution arrangements related to its non-Mifepristone products is irrelevant and overbroad harassment.

Physician Payments: Corcept claims that Teva's use of physician payments in other markets is relevant to its own payments here. Corcept cites *United States v. Teva Pharms. USA, Inc.*, asserting that Teva has previously described speaker fees as customary. *See* 13-cv-3702 (S.D.N.Y.), Dkt. 33 at 1, 3; Dkt. 141. But the existence of Teva's speaker programs for other products has no bearing on whether Corcept's payments to physicians in this market, for a disease with a small patient and physician population, far exceeded the norm, and whether the payments skyrocketed after Teva filed its ANDA, as Teva alleges.[2] *See e.g.*, Amend. Compl. ¶¶ 184-187.

Burden. Despite their irrelevance, Teva has agreed to produce materials regarding its other products, provided they are within the scope of materials Teva has otherwise agreed to search.[3] What is unacceptable to Teva, however, is baselessly and exponentially expanding the scope of its search to satisfy Corcept's desire to prove up a defense that the Supreme Court rejected long ago. That is a clear case of undue burden. Corcept attempts to dismiss the burden here by reciting the number of Teva's requests for production and interrogatories. A broad gesture to Teva's discovery efforts ***related to Korlym*** does nothing to mitigate the burden associated with Corcept's boundless request for discovery into hundreds of other products and markets. Corcept next claims Teva's concerns regarding burden is mere "speculation" that can be "address[ed] through reasonable and tailored custodians and search terms. But Corcept seeks four broad categories of information across Teva's **500** products—those requests will necessarily result in expansive search terms and custodians. "[W]hile the scope of discovery is broad, Rule 26(b)(1) does not countenance the kind of speculative fishing expedition called for in these document requests." *United States v. Real Property*, 2024 WL 4474867, at *11 (C.D. Cal. June 17, 2024). Corcept's requests would require adding countless custodians across Teva's organization, adding generic search terms that would hit on countless documents, and would require costly and time-consuming review of libraries worth of documents, most of which would have zero connection to this case. This overly broad discovery should be denied. *Moser v. Health Ins. Innovations, Inc.*, 2018 WL 6078308, at *4 (S.D. Cal. Nov. 20, 2018) (denying motion to compel where the "discovery requests at issue are overly

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[2] Teva has agreed to provide discovery into transfers of value, if any, related to Korlym—the only product at issue in this case.

[3] Corcept suggests that Teva "can produce non-custodial materials to address [its burden] concerns." Teva has already offered to produce non-custodial documents reflecting Teva's policies relating to (i) listing of patents in the FDA's Orange Book, (ii) maintaining patent infringement suits, (iii) payment of speaker fees, and (iv) exclusive dealing agreements. It is clear that Corcept is seeking far more.

broad on their face ... and do not appear to seek documents and information that meet the relevance standard of Federal Rule 26)(b)(1)").

The sweeping discovery that Corcept seeks related to Teva's non-mifepristone products is not relevant, overly broad, unduly burdensome, and disproportional to the needs of the case. As such, the Court should deny Corcept's motion to compel the production of documents in response to Corcept's RFP Nos. 1, 6, 15–16, 22, 43–47, and 59.

3. Parties' Views Regarding the Need For A Hearing

(a) Corcept's Position

Corcept believes that a hearing on this matter would be helpful to the Court and is prepared to discuss the relevance and importance of these documents, including to Corcept's defenses.

(b) Teva's Position

Teva believes that this matter may be resolved without a hearing, but if the Court would find a hearing helpful, Teva is prepared to discuss why the Court should deny Corcept's request for irrelevant and disproportional discovery which imposes undue burden on Teva.

4. Discovery Cut-Off Dates for Fact and Expert Discovery

The Court has not yet entered an order setting deadlines for the close of fact or expert discovery. However, in November 2024 the parties submitted a joint proposal as to the case schedule, in which the parties proposed November 21, 2025 as the close of fact discovery, and March 27, 2026 as the close of expert discovery.

5. Compliance With Meet and Confer Requirement

The parties met and conferred on this issue on April 21, 2025 via Zoom video call. Michael Shipley served as lead counsel for Teva, accompanied by Jen Joslin, Madison Scott Roemer, and Simeon Toronto. Mike Powell served as lead counsel for Corcept, accompanied by Brantley Pepperman and Steven Becker.

6. Attachments

An excerpted copy of Teva's Responses and Objections to Corcept's First Set of Requests for Production to Teva is attached as Exhibit A.

Respectfully submitted,

Dated: May 2, 2025

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/s/ Michael Shipley
Michael Shipley

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Dated: May 2, 2025

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